

REMARKS

This paper is in response to the Office Action dated February 17, 2009. Claims 1-6 and 10-14 are still pending in this paper. Applicants respectfully request the entry of the amendments and reconsideration of the application in view of the following remarks.

Discussion of Rejection of Claims 1-4 and 10-14 Under 35 U.S.C. § 103

The Office Action rejected Claims 1-4 and 10-14 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Thornton et al. (US Patent No. 6,551,350).

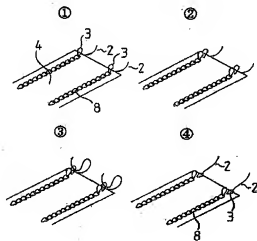
Claim 1 is directed to a tubular suture reinforcement material for an automatic suturing device, wherein

the tubular suture reinforcement material is formed by stacking two sheet-like materials and sewing together both ends of the two sheet-like materials using two chain stitches (intralooping stitches), each thread end at each sewing end is suitably extended, and the thread end is passed through an anterior loop continuous to the thread end, thereby preventing the thread from unraveling.

As it can be seen from Claim 1 above, the claimed invention adopts intralooping stitches (chain stitches), with which thread removal is significantly easier than with the running stitches of the known methods. Furthermore, the extended thread end is passed through an anterior loop continuous to the thread end, thereby preventing the thread from unraveling. This prevents the unintentional removal of the threads from the reinforcement materials.

The method for preventing threads from unraveling is detailed in Fig. 14 and paragraphs [0073] and [0074] of the Applicants' specification. Fig. 14 is reproduced below showing procedural steps for preventing unraveling of the thread ends.

Fig. 14



As can be seen from steps (2) to (4), the ends of the threads 2 are passed through the loops 3 and pulled tight. This method for preventing the threads from unraveling keeps the threads from being drawn out from the suture reinforcement material due to any tension that may be unintentionally applied to the thread ends 2. After the predetermined suturing process is completed, the threads are smoothly drawn out from the loops 3 by returning the thread ends 2 back through the loops 3 to the original position, or pulling the thread ends 2 to rip off the end of the fabric.

Thus, the claimed invention adopts a particular unravelment prevention method for the intralooping (chain) stitches, which allows significantly easy removal of threads compared with the known arts that use running (normal) stitches. The claimed invention also securely prevents the unintentional removal of threads from the reinforcement material.

Oi discloses a tubular suture reinforcement material made from stacking two sheet-like materials and sewing together ends of the sheet-like material to create a tubular structure using two threads.

However, Oi does not teach the claimed feature of sewing using chain stitches. Furthermore, Oi does not teach preventing a stitching from unraveling by extending each sewing end, passing each thread end through an anterior loop continuous to the thread end, thereby preventing the thread (stitching) from unraveling. Oi merely discloses sewing with conventional running stitch technique and knotting the thread end to prevent stitch from unraveling. Therefore, Oi fails to teach the chain stitch feature used in creating the tubular structure and chain stitching feature for preventing the threads from unraveling.

The Office Action asserted that Thornton remedies the deficiency of Oi by teaching the chain stitching concept using a single thread and that chain stitching creates a removable seam but also prevent unraveling until removal of the stitching is necessary. However, as explained below, Thornton does not teach the elements that are missing from Thornton. As such, the combination of the two references would not lead one of ordinary skill in the art to produce the presently claimed invention.

Thornton discloses a stent-graft that is subjected to a chain stitch using a thread-like coupling member to maintain the stent-graft in a folded state before placing and expanding the stent-graft at the desired site through endolumenal delivery (see column 14, lines 24-47, column 16, lines 12-21, and Figs. 10A, 11A of Thornton). However, Thornton fails to teach the

structural characteristic that prevents a thread from unraveling.

It is a well-known fact that a chain stitch itself can be easily released. Thornton merely discloses that, in order to maintain a stent-graft in a folded condition before implantation, the stent-graft is sewn using a chain stitch with a thread-like coupling member. Thornton is silent about providing an “unraveling prevention mechanism.” Furthermore, if the unraveling prevention mechanism of the present invention is applied to the stent-graft of Thornton, the thread-like coupling member will not be released in the lumen in the body, failing to expand the stent-graft in the lumen. Accordingly, Thornton does not suggest the unraveling prevention mechanism of the present invention.

Even a skilled artisan would not conceive the present invention from the combination of the disclosures of Oi and Thornton, and therefore the present claimed invention is unobvious over Oi in view of Thornton. As such, Oi and Thornton, in combination or alone, would not teach or suggest every feature of Claim 1 to one having ordinary skill in the art. With no additional evidence of teaching these features in the prior art, no *prima facie* obviousness has been established with regard to Claim 1 and its dependent claims 2-6 and 11-14.

Since Claim 10 discloses a method of manufacturing a tubular suture reinforcement material with features of Claim 1, the same rationale as described above in regard to Claim 1 can be applied to Claim 10. Thus, Oi and Thornton, in combination or alone, do not teach every feature of Claim 10 and Claim 10 is unobvious over the references.

Discussion of Rejection of Claims 5 Under 35 U.S.C. § 103

The Office Action rejected Claims 5 under 35 U.S.C. § 103(a) as being unpatentable over Oi in view of Thornton and further in view of Dalessandro et al. (US Patent No. 6,273,897). However, since **Dalessandro** adds nothing to address the deficiencies in the *prima facie* sharing of obviousness with regard to Claims 1 as asserted in the above section, claims dependent on Claim 1 including Claim 5 are also unobvious.

Discussion of Rejection of Claims 1 and 6 Under 35 U.S.C. § 103

The Office Action rejected Claims 1 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Igaki (US Patent No. 6,551,350) in view of Thornton.

The Office Action asserted that **Igaki** discloses a tubular structure reinforcement material, where the ends of the threads can be tied into a knot that is capable of forming a loop. However, Igaki fails to disclose chain stitching. The Office Action asserted that Thornton remedies the

deficiency of Igaki by teaching the chain stitching concept using and that chain stitching creates a removable seam but also prevent unraveling until removal of the stitching is necessary. However, as discussed above, Thornton does not teach the recited structure that prevents unraveling of the stitching. Accordingly, the cited combination would not lead one of ordinary skill in the art to produce the claimed invention.

Igaki discloses a tubular structure reinforcement material. However, Igaki merely discloses, in Fig. 1 (reproduced below) and column 3 lines 34-38, that suturing threads 4 and 5 form a stopper, such as a knot at an end adjacent to the shape maintaining support member 3, and is silent about passing end of the thread through a loop continuous to the thread. Igaki does not teach or suggest the mechanism for preventing the thread ends from unraveling of Claim 1.

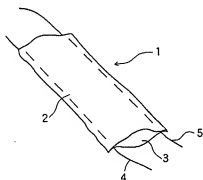


FIG.1

Furthermore, as described above, Thornton discloses the chain stitching, but does not teach the unraveling feature of passing the thread end through an anterior loop continuous to the thread end, thereby preventing a thread from unraveling.

As such, Igaki and Thornton in combination, do not teach every feature of Claim 1 to one having ordinary skill in the art. With no additional evidence of teaching these features in the prior art, no *prima facie* obviousness has been established with regard to Claim 1 and its dependent claim 6.

Dependent Claims

Although Applicants have not addressed all the issues of the dependent claims, Applicants respectfully submit that Applicants do not necessarily agree with the characterization and assessments of the dependent claims made by the Examiner, and Applicants believe that each claim is patentable on its own merits. Applicants respectfully submit that pursuant to 35 U.S.C. § 112, ¶4, the dependent claims incorporate by reference all the limitations of the claim to which

they refer and include their own patentable features, and are therefore in condition for allowance. Therefore, Applicants respectfully request the withdrawal of all claim rejections and prompts allowance of the claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested. If the Examiner has any questions which may be answered by telephone, he or she is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: May 15, 2009

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